Applicants also submit a marked-up version of Figure 8 with the changes shown in red as required under 37 C.F.R. §1.85. Applicants therefore request that the objection be reconsidered and withdrawn.

Specification

The Examiner has objected to the specification because it does not contain an abstract. Applicants have amended the specification as indicated above to add an abstract on a new page following the claims. Applicants therefore request that the objection be reconsidered and withdrawn.

The Examiner has further objected to the specification because it contains an embedded hyperlink and/or other form of browser-executable code. Applicants submit that the specification has been amended to remove the browser-executable code as indicated above. Applicants therefore request that the objection be reconsidered and withdrawn.

The Examiner has objected to the specification because there are blank lines on page 1, line 1 of the specification. Applicants are unclear as to what the Examiner is referring to, but have nonetheless submitted herewith a substitute page 1 which does not contain blank lines.

Priority

With respect to Applicants' claim for priority under 35 U.S.C. §119(a)-(d) to GB9800445.0, filed January 9, 1998, the Examiner has indicated that priority cannot be claimed because the filing date of the International application of which the present application is a continuation under §120, was filed on January 11, more than one year after the January 9 filing date of the GB9800445.0 application.

Applicants submit that the Manual of Patent Examining Procedure (MPEP) §201.13 (D)

onprovisional imprication mides—that "[1]f the last day of the 12 months is a Saturday.

Sunday, or Federal holiday...the U.S. nonprovisional application is in time if filed on the next succeeding business day." Applicants submit that the 12 month anniversary of the filing of

GB9800445.0 was **Saturday** January 9, 1999. The International application was filed on the next succeeding business day: January 11, 1999, and was filed in English, and designated the United States. Accordingly, Applicants submit that the claim for priority to GB9800445.0 is proper, and request that the Examiner's objection be reconsidered and withdrawn.

The Examiner further states that Applicants have not provided certified copies of the two GB applications from which the present application claims priority. Applicants submit that they are endeavoring to obtain certified copies of these two foreign applications, and will send them to the Examiner as soon as they are received.

Information Disclosure Statement

The Examiner has stated that the IDS filed on October 25, 2000 fails to comply with 37 C.F.R. §1.98(a)(2) which requires a legible copy of each U.S. and foreign patent or publication. The Examiner notes that several of the references cited in Applicants IDS were illegible, or incomplete. Applicants submit that they have submitted herewith a new form PTO-1449 along with legible and complete copies of the defective references for consideration. Applicants therefore request that the newly submitted references be entered into the application and considered by the Examiner.

Applicants believe that since the Information Disclosure References filed herewith are being re-filed at Examiner's request (originally filed references were deemed illegible), that no fee is due. Should Examiner decide otherwise, any requisite fee should be charged to Deposit Account Number 16-0085, Reference 5538/1010.

Rejection of Claims 10, 16, 24, and 26 Under 35 U.S.C. §112, Second Paragraph

for the purpose of expediting prosecution, claim 10 is herein cancelled without prejudice to pursuing this or a related claim in one or more continuing applications. Applicants submit that the rejection is now most and request that the rejection be reconsidered and withdrawn

The Examiner has rejected claim 24 under 35 U.S.C. §112 as being indefinite because the Examiner is unclear what "a peptide when selected by claim 17" means. Applicants submit that claim 24 has been amended to more clearly claim the peptide of the invention, and is no longer indefinite. Applicants request that the rejection be reconsidered and withdrawn.

The Examiner has rejected claim 26 under 35 U.S.C. §112 as being dependent on a non-elected claim. Applicants submit that, for the purpose of advancing prosecution, claim 26 has been cancelled without prejudice to pursuing this or a related claim in one or more continuing applications. Applicants submit that the rejection is now moot, and request that it be reconsidered and withdrawn.

The Examiner has rejected claim 16 under 35 U.S.C. §112 as being indefinite for the recitation of "and as given in". Applicants submit that claim 16 has been amended herein to more clearly recite "wherein the polypeptide allergen is a fragment of Fel d I selected from the group consisting of SEQ ID Nos. 1, 2, and 3", and as such, is not indefinite. Applicants request that the rejection be reconsidered and withdrawn.

Rejection of Claims 8-12, 15-16, 24, and 26 under 35 U.S.C. §102(b)

The Examiner had rejected claims 8-12, 15-16, 24, and 26 under 35 U.S.C. §102(b) as being anticipated by Briner et al. (PNAS 90: 7608 (1993)). The Examiner states that Briner et al. teach a plurality of peptides derived from Fel d I, including the peptides IPC-1, IPC-2 and Fel 1-2. The Examiner asserts that Briner et al. teach the peptides in a pharmaceutical composition comprising CFA, and its administration to mice. The Examiner asserts that since the amino acid sequence of Fel 1-2 taught by Briner et al. is identical to Applicants' SEQ ID NO: 6 encompassed by claim 16, the Fel 1-2 protein of Briner et al. inherently possesses the recited limitations of restriction to a class II MCH molecule and is able to induce a late phase response in an individual possessing the given MHC Class II molecule. Applicants respectfully transfer.

Applicants submit that the claims of the present invention recite a "composition comprising a plurality of peptides derived from a polypeptide allergen". The Examiner states that Briner et al. teach such a plurality. While Briner et al. teach several peptides, they do not

teach a "composition comprising a plurality of peptides derived from a polypeptide allergen" wherein "restriction to an MHC Class II molecule" can be demonstrated for "at least one of the peptides in the composition". Briner et al. teach that cells which have been pre-immunized with Fel d I are cultured "with recombinant chain 1 or with **each** of several overlapping peptides" (page 7611, first column, fourth paragraph). The only "composition comprising a plurality of peptides" taught by Briner et al. is a composition comprising IPC-1 and IPC-2 (page 7611, second column, first paragraph). Neither of the sequences of IPC-1 or IPC-2 is identical to any of the sequences (including SEQ ID NO: 6) of the present invention. Moreover, Briner et al. do not teach that at least one of the peptides in the composition, that is one of IPC-1 or IPC-2, is restricted to an MHC Class II molecule. Since the sequence of IPC-1 or IPC-2 is not identical to any of the sequences of the present invention, the Examiners assertion that the "composition" taught by Briner et al. would "inherently possess[es] the recited limitations of restriction to a class II MHC molecule…able to induce a late phase response in an individual possessing the given MHC Class II molecule" is in error. As the structures are not the same or substantially the same, identical function cannot be inferred.

Applicants therefore submit that Briner et al. do not teach each element of the claimed invention, and therefore do not anticipate the claimed invention. Applicants therefore request that the rejection be reconsidered and withdrawn.

CONCLUSION

Applicant submitthat all claims are allowable as written and respectfully request early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicants' attorney would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney of record.

Date:

<u>December</u> 5, 2002

Respectfully submitted,

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MARKED-UP VERSION OF AMENDMENTS:

In the Specification

The following is a list of known allergen sequences and database accession numbers (NCBI Entrez accession numbers). NCBI is the National Center for Biotechnology Information and is a division of the US National Institutes of Health. The NCBI [web site, from which access to the database may be sought, www.] database is on the World Wide Web at ncbi.nlm.nih.gov/. The allergens may be used as described above in order to identify MHC-restricted peptides capable of inducing LPR in individuals who possess a particular MHC molecule.

In the Claims

- or 9, or a pharmaceutical preparation according to Claim 11, wherein the polypeptide allergen is a fragment of Fel d I [and as given in] selected from the group consisting of SEQ ID Nos. 1, 2, and 3, or the composition contains the soluble MHC Class II-restricted peptides of the Fel d I derived peptides described in Figure 9.
- 24. (Twice Amended) A peptide [when selected by Claim 17] for use as an immunotherapeutic agent for desensitizing a patient to a polypeptide allergen capable of eliciting an allergic response in the patient, which patient possesses a particular MCH Class II molecule, selected by a method comprising (1) selecting a candidate peptide derived from the polypeptide allergen, (2) determining whether the candidate peptide demonstrates restriction to said MHC Class II molecule.

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